ARC 3330C

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 6, "General Pharmacy Practice," Iowa Administrative Code.

These amendments were approved at the August 30, 2017, regular meeting of the Board of Pharmacy.

Pursuant to Iowa Code section 17A.7(2), this proposed rule making is, in part, the result of an overall review of administrative rules. The proposed amendments clarify and rearrange content of rules in a more efficient manner, incorporate language from 2017 Iowa Acts, House File 305, signed into law during the 2017 Legislative Session of the 87th General Assembly, and provide for remote storage of records in certain circumstances.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on October 17, 2017. Such written materials may be sent to Terry Witkowski, Executive Officer, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 126.10, 126.11, 155A.6, 155A.13, 155A.27, 155A.28, 155A.31, and 155A.33 through 155A.36 and 2017 Iowa Acts, House File 305.

The following amendments are proposed.

ITEM 1. Amend subrule 6.7(2) as follows:

6.7(2) *Temporary absence of pharmacist.* In the temporary absence of the pharmacist, only the pharmacist in charge may designate pharmacy technicians or pharmacy support persons who may be present in the prescription department to perform technical or nontechnical functions, respectively, designated by the pharmacist in charge. Activities identified in subrule 6.7(3) may not be performed during such temporary absence of the pharmacist. A temporary absence is an absence of short duration not to exceed two hours.

a. No change.

b. A pharmacy technician or a pharmacy support person who is present in the pharmacy when the pharmacy is closed shall prepare and maintain in the pharmacy a log identifying each period of time that the pharmacy technician or pharmacy support person worked in the pharmacy while the pharmacy was closed and identifying each activity performed during that time period. Each entry shall be dated, and each daily record shall be signed by the pharmacy technician or pharmacy support person who prepared the record. The log shall be periodically reviewed by the pharmacist in charge, and documentation of such review shall be maintained for two years from the date of entry.

ITEM 2. Amend rule 657—6.8(124,155A) as follows:

657—6.8(124,155A) Prescription processing documentation. All prescriptions shall be dated and assigned a unique identification number that shall be recorded on the original prescription, except as provided in 657—subrule 21.5(1). The original prescription~~, whether transmitted orally, electronically, or in writing,~~ shall be retained by the pharmacy filling the prescription and shall be maintained in the original format as received by the pharmacy. ~~Refill~~ Dispensing documentation shall include date of fill

or refill and the initials or other unique identification of the pharmacist, pharmacist-intern, or technician in an approved tech-check-tech program. The name, strength, and ~~either the manufacturer's name or the~~ National Drug Code (NDC) of the actual drug product dispensed shall be maintained and be readily retrievable.

ITEM 3. Amend rule 657—6.9(124,155A) as follows:

657—6.9(124,155A) Transfer of prescription. The transmission of a prescription drug order from a pharmacy to a pharmacy engaged in centralized prescription filling or processing on behalf of the originating pharmacy pursuant to the requirements of 657—Chapter 18 shall not constitute the transfer of a prescription. Upon the request of a patient or the patient's caregiver, a pharmacy shall transfer original prescription drug order information and prescription refill information to a pharmacy designated by the patient or the patient's caregiver, central fill or processing pharmacies excepted, subject to the following requirements:

6.9(1) *Schedule III, IV, or V prescriptions.* The transfer of original prescription drug order information for controlled substances listed in Schedule III, IV, or V is permissible between pharmacies on a one-time basis except as provided in subrule ~~6.9(9)~~ 6.9(8).

6.9(2) No change.

6.9(3) *Communication.* The transfer is communicated directly between pharmacists, directly between pharmacist-interns under the direct supervision of pharmacists at the respective pharmacies, directly between a pharmacist and a pharmacist-intern under the direct supervision of a pharmacist, or as authorized in subrule ~~6.9(9)~~ 6.9(8). Following direct communication between authorized individuals as provided herein, the transferring pharmacist or pharmacist-intern may transmit the prescription and transfer information required under subrule 6.9(5) from the transferring pharmacy via facsimile. The receiving pharmacist or pharmacist-intern shall ensure the prescription transfer record maintained in the receiving pharmacy contains all of the information required under subrule ~~6.9(8)~~ 6.9(7).

6.9(4) *Prescriptions maintained.* Both the original and the transferred prescription drug orders are maintained for a period of two years from the date of last ~~refill~~ activity.

6.9(5) and **6.9(6)** No change.

~~**6.9(7)** *Controlled substance prescription status.* The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders that have been previously transferred.~~

~~**6.9(8)**~~ **6.9(7)** *Record of transfer received.* The pharmacist or pharmacist-intern receiving the transferred prescription drug order information shall:

a. No change.

b. Record on or with the transferred prescription drug order the following information:

(1) to (7) No change.

(8) If transferring a controlled substance prescription from a pharmacy utilizing a shared electronic database system as described in subrule ~~6.9(9)~~ 6.9(8) to a pharmacy outside that shared system, the pharmacy name, location, DEA registration number, and prescription number from which the prescription was originally filled.

~~**6.9(9)**~~ **6.9(8)** *Electronic transfer between pharmacies.* Pharmacies electronically accessing the same prescription drug order records via a real-time, on-line database may electronically transfer prescription information, including controlled substance prescription information, up to the maximum refills permitted by law and the prescriber's authorization, if the following requirements are met.

a. and *b.* No change.

c. For transfers of controlled substance prescriptions, all information requirements included in subrules 6.9(1) and 6.9(3) through ~~6.9(8)~~ 6.9(7) shall be satisfied in the electronic system. Transfers of controlled substance prescriptions shall also identify the pharmacy name, address, DEA registration number, and prescription number from which the prescription was originally filled.

ITEM 4. Amend subrule 6.10(1) as follows:

6.10(1) *Required information.* The label affixed to or on the dispensing container of any prescription drug or device dispensed by a pharmacy pursuant to a prescription drug order shall bear the following:

a. and *b.* No change.

c. Except as provided in 657—subrule 8.19(7) for epinephrine auto-injectors or 657—subrule 8.19(8) for opioid antagonists, the name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

d. to *f.* No change.

g. Unless otherwise directed by the prescriber, the label shall bear the name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)."

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)";

(3) If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the prescription container label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as "(interchangeable biological product) for (biological product)";

h. No change.

ITEM 5. Amend subrule 6.13(1) as follows:

6.13(1) *Information required.* A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. ~~The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing.~~ The ~~pharmacist~~ patient record system shall ~~be responsible for obtaining, recording, and maintaining~~ contain, at a minimum, the following information:

a. Full name of the patient ~~for whom the drug is intended~~;

b. Address and telephone number of the patient;

c. Patient's ~~age or~~ date of birth;

d. Patient's gender;

e. Known allergies;

f. ~~Significant patient information including a~~ A list of all prescription drug orders dispensed by the pharmacy during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date ~~received~~ dispensed, and the name of the prescriber; and

g. Pharmacist comments relevant to the ~~individual's drug therapy~~ patient's health care, including:

(1) Known drug reactions,

(2) Identified idiosyncrasies,

(3) Known chronic conditions or disease states of the patient,

(4) The identity of any other drugs, over-the-counter drugs, herbals, supplements, other alternative medications, or devices currently being used by the patient that may relate to prospective drug review.

ITEM 6. Amend rule 657—6.14(155A) as follows:

657—6.14(155A) Patient counseling and instruction. Every ~~general~~ pharmacy that is open to the public and located in Iowa shall post in every prescription pickup area, including in every drive-through prescription pickup lane, in a manner clearly visible to patients, a notice that Iowa law requires the pharmacist to discuss with the patient any ~~new~~ prescriptions dispensed to the patient that are new or a change in drug therapy. ~~The board shall provide a general pharmacy with the required signage. A~~

~~pharmacy that provides no direct patient access to the pharmacy department, commonly referred to as a "closed-door pharmacy," shall not be required to post the counseling notice.~~

6.14(1) *Counseling required.* Upon receipt of a new prescription drug order, or upon receipt of a change in drug therapy including but not limited to a change of dose, directions, or drug formulation, and following a prospective drug use review pursuant to rule 657—8.21(155A), a pharmacist or pharmacist-intern shall counsel each patient or patient's caregiver. An offer to counsel shall not fulfill the requirements of this rule. Patient counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

a. to *j.* No change.

6.14(2) and **6.14(3)** No change.

6.14(4) *Oral counseling not practicable.* If in the pharmacist's professional judgment oral counseling is not practicable, the pharmacist may select and use alternative forms of patient information which shall include information for the patient or patient's caregiver to contact the pharmacist for further consultation. The manner in which the patient or caregiver contacts the pharmacist shall not cause the patient to incur any expense. "Not practicable" refers to patient variables including, but not limited to, the absence of the patient or patient's caregiver, the patient's or caregiver's hearing impairment, or a language barrier. "Not practicable" does not include pharmacy variables such as inadequate staffing, technology failure, or high prescription volume. ~~Alternative forms of patient information may include written information leaflets, pictogram labels, video programs, or information generated by electronic data processing equipment. When used in place of oral counseling, alternative forms of patient information shall advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy by toll-free telephone or collect telephone call.~~ A combination of oral counseling and alternative forms of counseling is encouraged.

6.14(5) No change.

6.14(6) *Refusal of consultation.* A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient's or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that ~~the offer was accepted and that~~ counseling was provided.

ITEM 7. Amend rule 657—6.15(124,126) as follows:

657—6.15(124,126) Return of drugs and ~~other items~~ devices. For the protection of the public health and safety, prescription drugs and devices~~, controlled substances, and items of personal contact nature~~ may be returned to the pharmacy for reuse or resale only as herein provided:

6.15(1) *Integrity maintained.* Prescription drugs and devices may be returned, exchanged, or resold only if, in the professional judgment of the pharmacist, the integrity of the prescription drug or device has not in any way been compromised.

6.15(2) and **6.15(3)** No change.

~~**6.15(4)** *Personal contact items.* Pharmacy personnel shall not accept for reuse or resale any items of personal contact nature that have been removed from the original package or container after sale.~~

ITEM 8. Amend rule 657—6.16(124,155A) as follows:

657—6.16(124,155A) Records. Every ~~inventory or other~~ record required to be kept under Iowa Code chapters 124 and 155A or rules of the board shall be kept by the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the ~~inventory or~~ record or last activity except as specifically identified by law or rule. Controlled substances records shall be maintained in a readily retrievable manner in accordance with federal requirements and 657—Chapter 10. ~~Original hard-copy prescription and other pharmacy records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department unless such remote storage~~

~~is prohibited under federal law. A remote storage area shall be located within the same physical structure containing the licensed pharmacy department.~~

6.16(1) No change.

6.16(2) ~~*Prescriptions maintained*~~ *Storage of records.* ~~The original prescription drug order shall be maintained for a period of two years following the date of last activity on the prescription.~~ Original hard-copy prescriptions and other pharmacy records shall be maintained by the pharmacy for a minimum of two years from the date of the record in accordance with this subrule.

a. Records shall be maintained within the licensed pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the licensed pharmacy department, including at a remote location, if the pharmacy has retained an electronic copy of the records in the pharmacy that is immediately available and if the original records are available within 48 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

b. Records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department, including at a remote location, if the records are retrievable within 48 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

6.16(3) *Number imprinted.* The original hard-copy prescription shall be imprinted with the prescription or control number assigned to the prescription drug order, except as provided in 657—subrule 21.5(1).

6.16(4) *Alternative data retention system.* Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

a. and *b.* No change.

c. The information maintained in the alternative system is not obscured or rendered illegible due to security features of the original ~~hard-copy~~ record.